Quotient Sciences

Molecule to cure. Fast.™

Information sheet

Microbiology: Analytical Sciences

Our qualified and experienced microbiologists pride themselves on applying their knowledge and skills to ensure that pharmaceutical drug substances and drug products are safe and meet today's rigorous quality specifications and regulatory standards.

We also work closely with our own clinics and other clinical research units to provide a rapid results service within 24 to 48 hours to support extemporaneous preparations.

Facilities and equipment

Our purpose-built microbiology suite comprises a media preperation area (including a media autoclave, two microbiology assay rooms with microbiological safety cabinets and a laminar air flow cabinet), a Grade C cleanroom with a Grade A positive pressure isolator and a waste disposal area complete with discard autoclave. The suite is equipped with a range of equipment such as continually monitored incubators, sterility testing apparatus, water baths, cold storage and microscopes.

Services

For non-sterile and sterile drug substances and products, a full method development/validation service is offered to support the application of key microbiological techniques. As method development, validation and testing can all be performed at one Quotient facility, there is no need for time-consuming technology transfer activities. In addition, we are equipped to perform microbiological testing on radiolabelled, highly potent, cytotoxic and controlled substances.

Why choose Quotient Sciences?

- Our extensive experience permits testing of difficult products that have not previously been analyzed
- We are specialists at the microbial analysis of radiolabelled compounds and are able to handle cytotoxic, high potency compounds and controlled substances
- Our flexible approach allows us to offer both on-site microbiological testing and analysis of products made off-site

Microbial Analysis

Microbiological aspects of formulation development

- Preservative efficacy testing (Ph. Eur. 5.1.3, USP <51>), is used to help determine the necessary level of preservatives required in a formulation and then used to further determine if the correct level is maintained over the product shelf life.
- Customized challenge testing is mostly associated with unpreserved aqueous formulations. The Quotient team can design an appropriate challenge test for your product in order to determine the most suitable storage conditions and short-term shelf life, helping to ensure the product is safe throughout your clinical study.
- In-use testing is designed specifically for your product and its intended use.

Clinical Manufacturing Support

- Environmental monitoring in accordance with cGMP (current Good Manufacturing Practice), including settle plates, active air sampling, enumeration, isolation and, if required, the identification of isolates.
- Microbiological aspects of process simulation tests (media fills) including turbidity examination and fertility checks on media.
- Bioburden testing (Ph. Eur. 26.12, USP <61>, JP 4.05) of in-process samples is performed as part of the manufacture of a sterile product and determines the number of microorganisms present prior to sterilization.

Other microbiological services

- Drinking water testing – Quotient can test potable water to Drinking Water Inspectorate standards.
- Pharmaceutical water testing – water to be used in manufacturing or analysis can be tested in accordance to pharmacopoeial standards.
- Phenotype Identification of Microorganisms.

Quality control release testing

Suitability testing (validation), specific to each product is a requirement of all microbiological pharmacopoeia tests and the Microbiology Team at Quotient can advise on and perform this work.

- **Microbial enumeration** (Ph. Eur. 2.6.12, USP <61>, JP 4.05). The total Aerobic Microbial Count & Total combined Yeast/Moulds Count) by pour plate and membrane filtration.
- **Tests for specified microorganisms** (Ph. Eur 2.6.13, USP <62>, JP 4.05). Taking the intended use of your non-sterile product into consideration we can determine the most appropriate organisms to look for including Escherichia coli, Staphylococcus aureus and Salmonella species.
- **Sterility testing** (Ph. Eur. 2.6.1, USP <71>, JP 4.06). Whether tested by membrane filtration or direct inoculation, our sterility testing is performed in a positive pressure isolator housed in a Grade C room. The isolator is sanitized using a validated vaporized hydrogen peroxide (VHP) cycle.
- **The identification of isolates**. Quotient Sciences can identify isolates and determine whether they are objectionable in the product concerned.
- **Bacterial endotoxin testing** (gel-clot and kinetic) (Ph. Eur. 2.6.14, USP <85>, JP 4.01). Testing and reporting can be expediated within 24 hours for extemporaneous preparations if required.

Who is Quotient Sciences?

Quotient Sciences is a drug development and manufacturing accelerator providing integrated programs and tailored services across the entire development pathway. Cutting through silos across a range of drug development capabilities, we save precious time and money in getting drugs to patients. Everything we do for our customers is driven by an unswerving belief that ideas need to become solutions, molecules need to become cures, fast. Because humanity needs solutions, fast.

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